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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/792,155

03/02/2004

Jesse Salb

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4851

7590

06/29/2006

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EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/792,155	SALB ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/2/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The recitation of "the X moiety is an aryl substituted with at least one atom having a K-absorption edge of about 13 keV to about 90 keV" has priority to provisional 60/190,323 with a file date 3/16/00. The parent now 6,226,352 recites "the X moiety is arylamido" p 28, line 16 and does not include all aryl substituted moieties. Claim 50 has priority to provisional 60/190,323 with a file date 3/16/00.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 50 recites "the L moiety is an inhibitor of steric hindrance" which does not define or limit the inhibitor or what the function of inhibiting steric hindrance applies to. The claim language is indefinite because it is not defined as to what is encompassed and can be described as any small or nonsterically hindered structure.
4. Also, claim 50 recites "said cellular target" which does not limit the cellular target to a specific enzyme, protein, nucleic acid, lipid, etc... The claim is indefinite because it is not defined as to what is encompassed by cellular target.
5. In claim 50, the recitation of "aryl substituted" is indefinite because it is not clear what substitutions are encompassed thereby. Thus, "substituted" fails to clearly state

and define what chemical moieties are encompassed thereby. The definition, as described, leaves an endless number of possibilities for said substitution. It is unclear which chemical moieties are encompassed thereby, e.g. if this includes various diverse biomolecules, such as proteins, carbohydrates, lipids, various different small organics and heterocycles, etc.

6. Claim 50 recites the limitation "said cellular target". There is insufficient antecedent basis for this limitation in the claim.

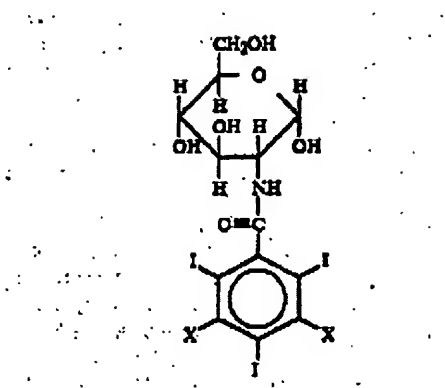
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claim 50 is rejected under 35 U.S.C. 102(b) as being anticipated by Bertoni (US 4,455,292).

Bertoni (US 4,455,292) discloses radiocontrast agent iodo-benzamido-glucopyranose such as metrizamide below (column 2, lines 34+).



7. Claim 50 is rejected under 35 U.S.C. 102(b) as being anticipated by Chien et al. (*Am. J. Physiol.* **1983**, 245, H693-H697).
8. Chien et al. (*Am. J. Physiol.* **1983**, 245, H693-H697) teaches of a fatty acid ¹²⁵I-paraphenylpentadecanoic acid (IPPA) utilized as myocardial imaging agents (p H693 abstract; p H694, fig 1.)

Claim Rejections - 35 USC § 103

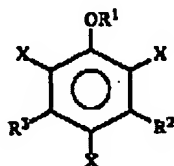
1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shefer et al. (US 4,887,604) in view of Sovak et al. (US 4,243,653).
3. Shefer et al. (US 4,887,604) disclosed an iodine contrast agents for energy subtraction or dual energy medical imaging system used to image a body part

impregnated with a radio-opaque dye (column 2, lines 1-10; lines 50-53). The radio-opaque dye contains iodine which has a sharp K-edge at 33.16Kev (column 6, lines 47-52). Shefer et al. (US 4,887,604) does not disclose a pyranose or furanose substituted radio-opaque dye.

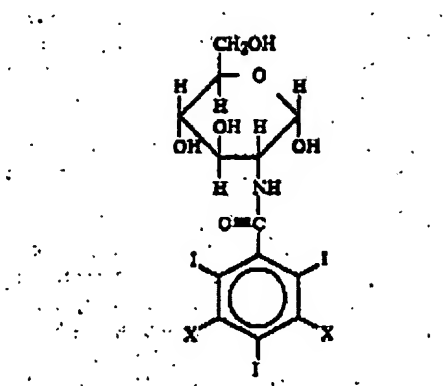
4. Sovak et al. (US 4,243,653) discloses a non-ionic polyiodo sugar substituted aniline as contrast media with the structure below: where X may be iodine, R¹ may be a sugar such as furanose or pyranose and R³ may be amino (column 2, lines 31+).



5. Claim 50 is rejected under 35 U.S.C. 103(a) as being obvious over Shefer et al. (US 4,887,604) in view of Bertoni (US 4,455,292).

6. Shefer et al. (US 4,887,604) disclosed an iodine contrast agents for energy subtraction or dual energy medical imaging system used to image a body part impregnated with a radio-opaque dye as well as that listed above (column 2, lines 1-10; lines 50-53) but does not disclose a pyranose or furanose substituted radio-opaque dye.

7. Bertoni (US 4,455,292) discloses radiocontrast agents iodo-benzamido-glucopyranose such as metrizamide below (column 2, lines 34+).



8. At the time of the invention it would have been obvious to one ordinarily skilled in the art to combine the anon-ionic polyiodo sugar substituted aniline as contrast media of Sovak et al. (US 4,243,653) for its stability, low toxicity, increased solubility in water and ease of preparation with the radio-opaque dye of Shefer et al. (US 4,887,604) that contains an iodine substituent that has a sharp K-edge at 33.16Kev.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 50 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 64 of U.S. Patent No. 6,226,352 in view of Bertoni (US 4,455,292). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application and to U.S. Patent No. 6,226,352 are drawn to a method of regenerating a functional image using the same composition of a radio-opaque imaging agent having the general formula S-L-X where S is a cellular molecule binding moiety, X is a radio-opaque moiety, and L is the linking moiety. The claims of the present application are further limited to claim more specifically that the binding moiety S is pyranose and furanose or

others listed in claim 50, X is an aryl substituted with at least one atom having a K-absorption edge of 13 keV to 91 keV and L is an inhibitor of steric hindrance.

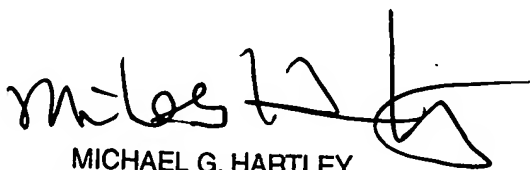
Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER